

103^D CONGRESS
2^D SESSION

H. R. 3874

To amend various Acts to establish offices of women's health within certain agencies.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 22, 1994

Ms. SNOWE introduced the following bill; which was referred jointly to the
Committees on Energy and Commerce and Ways and Means

A BILL

To amend various Acts to establish offices of women's health
within certain agencies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Women's Health Office
5 Act of 1994".

6 **SEC. 2. PUBLIC HEALTH SERVICE OFFICE OF WOMEN'S**
7 **HEALTH.**

8 Part A of title III of the Public Health Service Act
9 (42 U.S.C. 241 et seq.) is amended by adding at the end
10 the following section:

1 “PUBLIC HEALTH SERVICE OFFICE OF WOMEN’S HEALTH

2 “SEC. 310A. (a) ESTABLISHMENT OF OFFICE.—

3 There is established an Office of Women’s Health (here-

4 after referred to in this section as the ‘Office’) within the

5 Office of the Assistant Secretary for Health.

6 “(b) ASSISTANT SECRETARY.—There shall be in the

7 Department of Health and Human Services a Deputy As-

8 sistant Secretary for Women’s Health, who shall be the

9 head of the Office. The Secretary, acting through such

10 Deputy Assistant Secretary, shall carry out this section.

11 “(c) DUTIES.—The Secretary, acting through the Of-

12 fice, shall, with respect to the health concerns of women—

13 “(1) establish short-range and long-range goals

14 and objectives and coordinate all other activities

15 within the Department of Health and Human Serv-

16 ices that relate to disease prevention, health pro-

17 motion, service delivery, and research concerning

18 women;

19 “(2) advise the Assistant Secretary for Health

20 concerning scientific, legal, ethical, and policy issues

21 relating to women’s health;

22 “(3) monitor Public Health Service agency and

23 regional activities regarding women’s health, and

24 coordinate activities of such agency Offices of

25 Women’s Health;

1 “(4) establish a women’s health resource center
2 to facilitate the exchange of information regarding
3 matters relating to health information and health
4 promotion, preventive health services, and education
5 in the appropriate use of health care, to facilitate ac-
6 cess to such information, to assist in the analysis of
7 issues and problems relating to such matters, and to
8 provide technical assistance with respect to the ex-
9 change of such information (including facilitating
10 the development of materials for such technical as-
11 sistance); and

12 “(5) coordinate efforts to promote women’s
13 health programs and policies in the voluntary and
14 corporate sectors.

15 “(d) REPORTS.—Not later than January 31, 1995,
16 and January 31 of each second year thereafter, the Sec-
17 retary shall prepare and submit to the appropriate com-
18 mittees of Congress a report describing the activities car-
19 ried out under this section during the preceding 2 fiscal
20 years.

21 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
22 purpose of carrying out this section, there are authorized
23 to be appropriated such sums as may be necessary for
24 each of the fiscal years 1994 through 1996.”.

1 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVEN-**
2 **TION OFFICE OF WOMEN'S HEALTH.**

3 Part A of title III of the Public Health Service Act
4 (42 U.S.C. 241 et seq.) (as amended by section 2) is fur-
5 ther amended by adding at the end the following section:

6 “CENTERS FOR DISEASE CONTROL AND PREVENTION

7 OFFICE OF WOMEN'S HEALTH

8 “SEC. 310B. (a) ESTABLISHMENT.—There is estab-
9 lished within the Office of the Director of the Centers for
10 Disease Control and Prevention an office to be known as
11 the Office of Women's Health (hereafter referred to in this
12 section as the ‘Office’). The Office shall be headed by a
13 director who shall be appointed by the Director of the
14 Centers.

15 “(b) PURPOSE.—The Director of the Office shall—

16 “(1) determine the current level of the Centers
17 activity regarding women's health conditions, across
18 age, biological, and sociocultural contexts, in all as-
19 pects of the Centers work, including prevention pro-
20 grams, public and professional education, services,
21 and treatment;

22 “(2) establish short-range and long-range goals
23 and objectives for women's health and coordinate all
24 other activities within the Centers that relate to pre-
25 vention, research, education and training, service de-
26 livery, and policy development;

1 “(3) identify projects in women’s health that
2 should be conducted or supported by the National
3 Centers;

4 “(4) consult with health professionals, non-gov-
5 ernmental organizations, consumer organizations,
6 women’s health professionals, and other individuals
7 and groups, as appropriate, on the policy of the Cen-
8 ters with regard to women; and

9 “(5) coordinate agency activities on women’s
10 health with the Public Health Service Office of
11 Women’s Health established under section 310A.

12 “(c) COORDINATING COMMITTEE.—

13 “(1) ESTABLISHMENT.—In carrying out sub-
14 section (b), the Director of the Office shall establish
15 a committee to be known as the Coordinating Com-
16 mittee on Research on Women’s Health (hereafter
17 referred to in this subsection as the ‘Coordinating
18 Committee’).

19 “(2) COMPOSITION.—The Coordinating Com-
20 mittee shall be composed of the Directors of the
21 National Centers.

22 “(3) CHAIRPERSON.—The Director of the Of-
23 fice shall serve as the chairperson of the Coordinat-
24 ing Committee.

1 “(4) DUTIES.—With respect to women’s health,
2 the Coordinating Committee shall assist the Director
3 of the Office in—

4 “(A) identifying the need for programs and
5 activities that focus on women’s health;

6 “(B) identifying needs regarding the co-
7 ordination of activities, including intramural
8 and extramural multidisciplinary activities; and

9 “(C) making recommendations to the Di-
10 rector of the Centers for Disease Control and
11 Prevention concerning findings made under
12 subparagraphs (A) and (B).

13 “(d) REPORTS.—Not later than January 31, 1995,
14 and January 31 of each second year thereafter, the Direc-
15 tor shall prepare and submit to the Director of the Public
16 Health Service Office of Women’s Health, a report de-
17 scribing the activities carried out under this section during
18 the preceding 2 fiscal years.

19 “(e) DEFINITION.—As used in this section the term
20 ‘women’s health conditions’, with respect to women of all
21 age, ethnic, and racial groups, means all diseases, dis-
22 orders, and conditions—

23 “(1) unique to, more serious, or more prevalent
24 in women; and

1 “(2) for which the factors of medical risk or
2 type of medical intervention are different for women,
3 or for which it is unknown whether such factors or
4 types are different for women.”.

5 **SEC. 4. AGENCY FOR HEALTH CARE POLICY AND RE-**
6 **SEARCH OFFICE OF WOMEN’S HEALTH.**

7 Part C of title IX of the Public Health Service Act
8 (42 U.S.C. 299c et seq.) is amended—

9 (1) by redesignating section 927 as section 928;
10 and

11 (2) by inserting after section 926 the following
12 section:

13 **“SEC. 927. OFFICE OF WOMEN’S HEALTH.**

14 **“(a) ESTABLISHMENT.—**There is established within
15 the Office of the Director of the Agency for Health Care
16 Policy and Research an office to be known as the Office
17 of Women’s Health (hereafter referred to in this section
18 as the ‘Office’). The Office shall be headed by a Director
19 who shall be appointed by the Director of the Agency.

20 **“(b) PURPOSE.—**The Director of the Office shall—

21 **“(1)** determine the current Agency level of ac-
22 tivity regarding women’s health, across age, biologi-
23 cal, and sociocultural contexts, in all aspects of
24 Agency work, including drafting clinical practice
25 guidelines, and conducting research into patient out-

1 comes, delivery of health care services, and access to
2 health care;

3 “(2) establish short-range and long-range goals
4 and objectives for research important to women’s
5 health and coordinate all other activities within the
6 Agency that relate to health services and medical
7 effectiveness research;

8 “(3) identify projects in women’s health that
9 should be conducted or supported by the Agency;

10 “(4) consult with health professionals, non-gov-
11 ernmental organizations, consumer organizations,
12 women’s health professionals, and other individuals
13 and groups, as appropriate, on Agency policy with
14 regard to women; and

15 “(5) coordinate agency activities on women’s
16 health with the Public Health Service Office of
17 Women’s Health established under section 310A.

18 “(c) COORDINATING COMMITTEE.—

19 “(1) ESTABLISHMENT.—In carrying out sub-
20 section (b), the Director of the Office shall establish
21 a committee to be known as the Coordinating Com-
22 mittee on Research on Women’s Health (hereafter
23 referred to in this subsection as the ‘Coordinating
24 Committee’).

1 “(2) COMPOSITION.—The Coordinating Com-
2 mittee shall be composed of the Directors of the
3 Offices.

4 “(3) CHAIRPERSON.—The Director of the Of-
5 fice shall serve as the chairperson of the Coordinat-
6 ing Committee.

7 “(4) DUTIES.—With respect to research on
8 women’s health, the Coordinating Committee shall
9 assist the Director of the Office in—

10 “(A) identifying the need for such re-
11 search, and making an estimate each fiscal year
12 of the funds needed to adequately support the
13 research;

14 “(B) identifying needs regarding the co-
15 ordination of research activities, including in-
16 tramural and extramural multidisciplinary ac-
17 tivities; and

18 “(C) making recommendations to the Di-
19 rector of the Agency for Health Care Policy and
20 Research concerning findings made under sub-
21 paragraphs (A) and (B).

22 “(d) REPORTS.—Not later than January 31, 1995,
23 and January 31 of each second year thereafter, the Direc-
24 tor shall prepare and submit to the Director of the Public
25 Health Service Office of Women’s Health, a report de-

1 scribing the activities carried out under this section during
2 the preceding 2 fiscal years.”.

3 **SEC. 5. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
4 **TION OFFICE OF WOMEN’S HEALTH.**

5 Title VII of the Social Security Act (42 U.S.C. 901
6 et seq.) is amended by adding at the end the following
7 section:

8 “OFFICE OF WOMEN’S HEALTH

9 “SEC. 712. (a) ESTABLISHMENT.—There is estab-
10 lished within the Office of the Administrator of the Health
11 Resources and Services Administration an office to be
12 known as the Office of Women’s Health (hereafter re-
13 ferred to in this section as the ‘Office’). The Office shall
14 be headed by a director who shall be appointed by the Di-
15 rector of the Administration.

16 “(b) PURPOSE.—The Director of the Office shall—

17 “(1) determine the current agency level of activ-
18 ity regarding women’s health across age, biological,
19 and sociocultural contexts;

20 “(2) establish short-range and long-range goals
21 and objectives for women’s health and coordinate all
22 other activities within the agency that relate to
23 health care provider training, health service delivery,
24 research, and demonstration projects;

25 “(3) identify projects in women’s health that
26 should be conducted or supported by the Bureaus;

1 “(4) consult with health professionals, non-gov-
2 ernmental organizations, consumer organizations,
3 women’s health professionals, and other individuals
4 and groups, as appropriate, on agency policy with
5 regard to women; and

6 “(5) coordinate agency activities on women’s
7 health with the Public Health Service Office of
8 Women’s Health established under section 310A of
9 the Public Health Service Act.

10 “(c) COORDINATING COMMITTEE.—

11 “(1) ESTABLISHMENT.—In carrying out sub-
12 section (b), the Director of the Office shall establish
13 a committee to be known as the Coordinating Com-
14 mittee on Research on Women’s Health (hereafter
15 referred to in this subsection as the ‘Coordinating
16 Committee’).

17 “(2) COMPOSITION.—The Coordinating Com-
18 mittee shall be composed of the Directors of the
19 Bureaus.

20 “(3) CHAIRPERSON.—The Director of the Of-
21 fice shall serve as the Chairperson of the Coordinat-
22 ing Committee.

23 “(4) DUTIES.—With respect to research on
24 women’s health, the Coordinating Committee shall
25 assist the Director of the Office in—

1 “(A) identifying the need for programs and
2 activities that focus on women’s health;

3 “(B) identifying needs regarding the co-
4 ordination of activities, including intramural
5 and extramural multidisciplinary activities; and

6 “(C) making recommendations to the Di-
7 rector of the Centers for Disease Control and
8 Prevention concerning findings made under
9 subparagraphs (A) and (B).

10 “(d) REPORTS.—Not later than January 31, 1995,
11 and January 31 of each second year thereafter, the Direc-
12 tor of the Office shall prepare and submit to the Director
13 of the Public Health Service Office of Women’s Health,
14 a report describing the activities carried out under this
15 section during the preceding 2 fiscal years.”.

16 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**
17 **WOMEN’S HEALTH.**

18 Chapter IX of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 391 et seq.) is amended by adding at the
20 end the following section:

21 **“SEC. 906. OFFICE OF WOMEN’S HEALTH.**

22 “(a) ESTABLISHMENT.—There is established within
23 the Office of the Commissioner of the Food and Drug Ad-
24 ministration an office to be known as the Office of Wom-
25 en’s Health (hereafter referred to in this section as the

1 ‘Office’). The Office shall be headed by a Director who
2 shall be appointed by the Commissioner of the Administra-
3 tion.

4 “(b) PURPOSE.—The Director of the Office shall—

5 “(1) determine current Commission levels of ac-
6 tivity regarding women’s participation in clinical
7 trials the study of gender differences in the testing
8 of drugs, medical devices, and biological products,
9 across, age, sociocultural, and, where deemed appro-
10 priate, biological contexts;

11 “(2) establish short-range and long-range goals
12 and objectives for adequate inclusion of women in all
13 Commission protocols and policies;

14 “(3) provide guidance or criteria for drug and
15 device manufacturers to use in determining the ex-
16 tent and sufficiency of female representation in clini-
17 cal trials;

18 “(4) consult with pharmaceutical manufactur-
19 ers, health professionals with expertise in women’s
20 issues, consumer organizations, and women’s health
21 professionals on Commission policy with regard to
22 women;

23 “(5) make annual estimates of funds needed to
24 monitor clinical trials in accordance with needs that
25 are identified; and

1 “(6) coordinate Commission activities on wom-
2 en’s health with the Public Health Service Office of
3 Women’s Health established under section 310A of
4 the Public Health Service Act.

5 “(c) COORDINATING COMMITTEE.—

6 “(1) ESTABLISHMENT.—In carrying out sub-
7 section (b), the Director of the Office shall establish
8 a committee to be known as the Coordinating Com-
9 mittee on Women’s Health (hereafter referred to in
10 this subsection as the ‘Coordinating Committee’).

11 “(2) COMPOSITION.—The Coordinating Com-
12 mittee shall be composed of the Directors of the
13 Food and Drug Administration Centers.

14 “(3) CHAIRPERSON.—The Director of the Of-
15 fice shall serve as the Chairperson of the Coordinat-
16 ing Committee.

17 “(4) DUTIES.—With respect to studies on wom-
18 en’s health, the Coordinating Committee shall assist
19 the Director of the Office in—

20 “(A) identifying the need for further stud-
21 ies in specific areas of women’s health that fall
22 within the mission of the Commission, and de-
23 veloping strategies to foster such studies;

1 “(B) identifying needs regarding the co-
2 ordination of Commission activities, including
3 intramural and extramural studies;

4 “(C) maintaining the Commission’s focus
5 in areas of importance to women;

6 “(D) supporting the development of meth-
7 odologies to determine the circumstances in
8 which obtaining data specific to women (includ-
9 ing data relating to the age of women and the
10 membership of women in ethnic or racial
11 groups) is an appropriate function of clinical
12 trials of treatments and therapies;

13 “(E) supporting the development and ex-
14 pansion of clinical trials of treatments and
15 therapies for which obtaining such data has
16 been determined to be an appropriate function;
17 and

18 “(F) encouraging the Food and Drug Ad-
19 ministration Centers to conduct and support
20 such studies, including such clinical trials.

21 “(d) REPORTS.—Not later than January 31, 1995,
22 and January 31 of each second year thereafter, the Direc-
23 tor shall prepare and submit to the Director of the Public
24 Health Service Office of Women’s Health, a report de-

- 1 scribing the activities carried out under this section during
- 2 the preceding 2 fiscal years.”.

○